

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



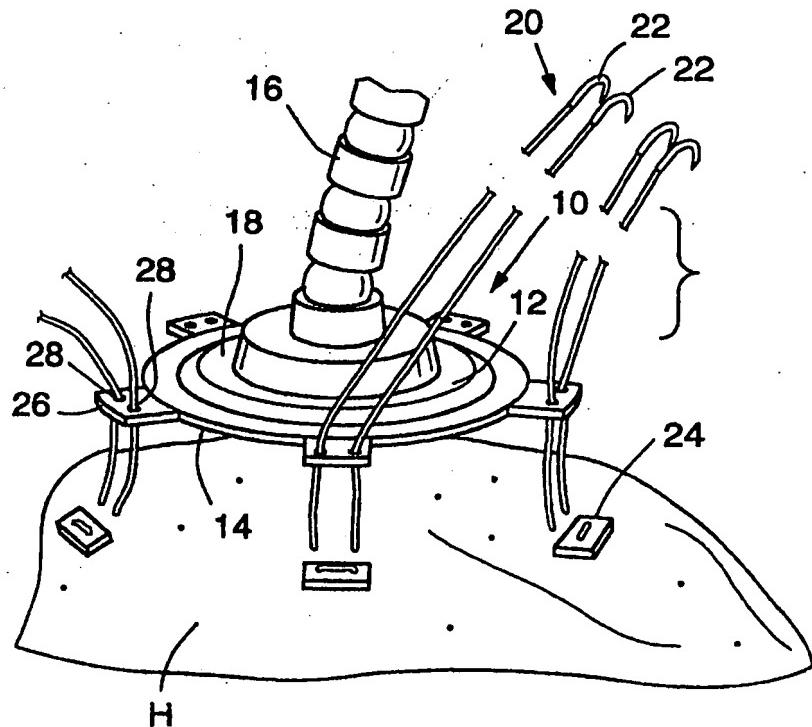
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/00		A2	(11) International Publication Number: WO 99/60929
			(43) International Publication Date: 2 December 1999 (02.12.99)
(21) International Application Number: PCT/US99/11654		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 27 May 1999 (27.05.99)			
(30) Priority Data: 09/087,511 29 May 1998 (29.05.98) 09/109,924 2 July 1998 (02.07.98)		US	Published <i>Without international search report and to be republished upon receipt of that report.</i>
(71) Applicant: GUIDANT CORPORATION [US/US]; 1360 O'Brien Drive, Menlo Park, CA 94025-1436 (US).			
(72) Inventors: SPENCE, Paul, A.; 5818 Orion Road, Louisville, KY 40222 (US). WILLIAMSON, Warren, P., IV; 101 Southbend Court, Loveland, OH 45140 (US).			
(74) Agents: EQUITZ, Alfred, A. et al.; Limbach & Limbach L.L.P., 2001 Ferry Building, San Francisco, CA 94111-4262 (US).			

(54) Title: DEVICE TO PERMIT OFFPUMP BEATING HEART CORONARY BYPASS SURGERY

(57) Abstract

Mechanical elements (such as sutures or staples, or adhesive, or both, are used in conjunction with or in place of suction to releasably attach to a heart a cup (or other element) for manipulating the heart (which can be a beating heart) during cardiac surgery. In preferred embodiments, a system which embodies the invention includes a cup configured to engage and exert force (e.g., suction force) on a heart to move the heart to a position suitable for surgery. One form of the system is useful in the performance of minimally invasive surgery.



AMA

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

and methods described.

Most particularly, the means and method described in those applications include using a gross support to support the heart and a means for engaging a selected section of the heart to immobilize that selected section as a surgery target while permitting non-engaged sections of the heart to move in a manner whereby essentially unabated cardiac output is maintained while the heart is regionally immobilized.

The gross support means disclosed in the application filed on May 29, 1998 includes a flexible cup that can move in a plurality of planes and which has a flexible rim for engaging the heart. The cup is releasably attached to the heart. One means for releasably attaching the cup to the heart includes suction applied by the cup to the heart. Suction is the best mode disclosed in the just-mentioned patent application.

As suction is readily available in most operating rooms, this is an effective means for releasably attaching the elements to the heart. However, this means can be improved.

Therefore, there is a need for a means and method for improving the releasable attachment between the elements of the heart manipulation system disclosed in the incorporated patent applications and the heart.

The suction system disclosed in the incorporated patent applications can also benefit by being backed up whereby the heart will remain in the desired position and orientation even if vacuum is lost or degraded.

Therefore, there is a need to provide a means for backing up the vacuum system used in the incorporated patent applications to releasably attach the elements of the system to the heart.

Operation of the heart was discussed in the incorporated 5 patent applications and reference is made thereto for such disclosure so it will not be repeated here.

Recently, there has been interest in minimally invasive coronary bypass surgery. This is not surprising since a median sternotomy and a run on the cardiopulmonary bypass pump are not 10 well tolerated by some patients, combined with the added cost of coronary bypass equipment and staff. The procedure results in considerable recovery time and is associated with a risk of death and major complication. While the ultimate goal is to provide bypass to all vessels by port access (like gallbladder surgery) 15 and to eliminate the need for cardiopulmonary bypass, a more limited but reasonable option for the next number of years will be to perform bypass off pump with an incision (sternotomy or thoracotomy). A tool which could allow performance of multivessel off pump bypass would be most helpful.

20 Therefore, the incorporated patent applications disclosed a heart retractor which will support the heart in position for minimally invasive coronary bypass surgery of coronary arteries, including the circumflex coronary artery, in a manner that will not damage the heart yet will provide easy access to the surgical 25 target without requiring the heart to be stopped yet without unduly constraining the heart.

Therefore, there is a need to provide a means for backing up the vacuum system used in the incorporated patent applications to releasably attach the elements of the system to the heart.

Operation of the heart was discussed in the incorporated 5 patent applications and reference is made thereto for such disclosure so it will not be repeated here.

Recently, there has been interest in minimally invasive coronary bypass surgery. This is not surprising since a median sternotomy and a run on the cardiopulmonary bypass pump are not 10 well tolerated by some patients, combined with the added cost of coronary bypass equipment and staff. The procedure results in considerable recovery time and is associated with a risk of death and major complication. While the ultimate goal is to provide bypass to all vessels by port access (like gallbladder surgery) 15 and to eliminate the need for cardiopulmonary bypass, a more limited but reasonable option for the next number of years will be to perform bypass off pump with an incision (sternotomy or thoracotomy). A tool which could allow performance of multivessel off pump bypass would be most helpful.

20 Therefore, the incorporated patent applications disclosed a heart retractor which will support the heart in position for minimally invasive coronary bypass surgery of coronary arteries, including the circumflex coronary artery, in a manner that will not damage the heart yet will provide easy access to the surgical 25 target without requiring the heart to be stopped yet without unduly constraining the heart.

These means and methods can also be improved by having additional means and methods for releasably attaching the elements of the systems to the heart during minimally invasive surgery.

5 Objects of the Invention

It is main object of the present invention to improve the performance of the system for manipulating a heart during cardiac surgery which was disclosed in the incorporated patent applications.

10 It is another object of the present invention to improve the performance of the retractors disclosed in the parent disclosures.

15 It is another object of the present invention to improve the performance of the retractors disclosed in the parent disclosures by providing additional means for releasably attaching the elements of those systems to the heart.

It is a more specific object of the present invention to provide mechanical means for releasably attaching elements of a system for manipulating a heart during cardiac surgery.

20 It is a more specific object of the present invention to provide adhesive means for releasably attaching elements of a system for manipulating a heart during cardiac surgery.

The objects set forth in the incorporated applications are incorporated herein by reference.

25 Summary of the Invention

These, and other, objects are achieved by providing

mechanical and/or adhesive means for releasably attaching the elements of a system for manipulating a heart during cardiac surgery.

Brief Description of the Drawing Figures

5 Figure 1 illustrates a suspension head mechanism such as disclosed in the incorporated patent application for lifting the heart.

Figure 2 illustrates one mechanical means for releasably attaching the suspension head to the heart as including a suture.

10 Figure 3 illustrates one mechanical means for releasably attaching the suspension head to the heart as including a staple.

Figure 4 is another view of the staple shown in Figure 3 in the formed condition.

Figure 5 illustrates a staple removing element.

15 Figure 6 illustrates one mechanical means for releasably attaching the suspension head to the heart as including a suture.

Figure 7 is another form of the suture mechanical attaching means shown in Figure 6.

20 Figure 8 illustrates an adhesive means for attaching an element of the heart manipulation system to the heart.

Detailed Description of the Preferred Embodiment of the Invention

The operation of a heart was discussed in the incorporated patent applications, and reference thereto is made for such discussion. Furthermore, the discussion of the various elements of the heart manipulation system were also fully discussed in the incorporated material, and reference is made thereto.

The improvement in the heart manipulation system which is the subject of the present invention utilizes either mechanical or adhesive means to releasably attach an element of the heart manipulation system to the heart. These means can be used in 5 place of or in addition to the means disclosed in the incorporated patent applications.

As shown in Figure 1, a special cup 10 is used to attach various elements of the heart manipulation system to the beating heart H in a manner that permits the heart and the myocardium to 10 move during heart operation without unduly affecting the attachment of the element to the heart. The cup 10 can be adapted to apply suction to the heart, but need not and can be designed to have several degrees of freedom whereby the heart can move without undue restriction from cup 10. Specifically, cup 10 has a 15 flexible wall 12 and a flexible rim 14 and is attached to an arm 16 at an apex portion 18 of the cup. The flexible wall permits the cup to move in a plurality of planes so the heart can move relative to arm 16.

The means for releasably attaching cup 10 to the heart can 20 include mechanical means. As used herein, the term "mechanical means" includes sutures, staples and other such mechanical elements and fasteners as opposed to suction and chemical means.

One form of mechanical means for releasably attaching elements of the heart manipulation system to the heart includes 25 sutures 20. Sutures 20 include needles 22 which are threaded through the heart manipulation system element, such as cup 10,

and then through the heart tissue, and then back through the heart tissue and back through the system element and out of the patient. Sutures 20 can also include an element, such as pledget 24 for holding the suture in place on the heart and for spreading 5 out the force applied by the suture to the heart tissue. The sutures can be set in any manner known to those skilled in the art. Once set, the sutures are tied off and then serve as a means for attaching the system element to the heart. The sutures are cut when the element is to be released from the heart.

10 As shown in Figure 1, the element, such as cup 10, can include extensions, such as extension 26, having suture-accommodating holes 28 defined therethrough. However, the element need not include the extensions, and the holes 28 can be defined in the element itself or the sutures can be drawn through the 15 element without the need of such holes 28 without departing from the scope of the present disclosure.

While the sutures are shown in Figure 2 as extending through an extension on the element, these sutures could be sewn through the element itself without departing from the scope of the 20 present invention. In fact, the sutures need not be located near the perimeter of the element, but could be placed in any suitable location on the element without departing from the scope of the present invention. The sutures can be manipulated in any suitable manner and can take the form of any suture known to those skilled 25 in the art without departing from the scope of the present disclosure. Those skilled in the art will understand what type of

suture works best in any given application based on their own knowledge and the teaching of the present invention and the present disclosure. Accordingly, the term "suture" is intended to cover any suture known to those skilled in the art that will work 5 in the application disclosed herein.

Yet another form of mechanical means for releasably attaching an element of the heart manipulation system to the heart is shown in Figures 3 and 4 as including a staple 30. Staple 30 is set and formed according to known procedures from 10 the unformed condition shown in Figure 3 to the formed configuration shown in Figure 4. Staples, such as those used to close skin can also be used and still be within the teaching of this invention. An extension 32 is included on the heart manipulation system element, such as cup 10, and has a distal end 15 34 with a neck 36 defined therein. A tab 38 is located on the distal end and includes a groove 40 that permits a portion 41 of a staple removing tool, such as tool 42 shown in Figure 5, to be inserted beneath the staple for removing that staple from the formed configuration shown in Figure 4. Once the staples are 20 removed, the element can be released from attachment to the heart. Portion 41 is manipulated by handle 44 via pivot 46 to unform the staple to release the staple from the heart.

Yet another form of mechanical means is illustrated in Figures 6 and 7 as a plurality of anchor wires 50 located inside 25 the element being releasably attached to heart H. Each anchor wire 50 include a curled, pre-shaped end 52 which curls up inside

the heart tissue once the wire is inserted into the tissue to fasten the element to the heart. The anchor wires extend inside the element from apex 18 to and out of rim 14 and the curled bias thereof is overcome by the inside surface of the element as indicated at end 52' shown in Figure 6. The wire curls as it exits the element and enters the heart tissue. A plurality of wires can be used as indicated in Figure 7, and the wires can be used in conjunction with, or in place of, suction and/or other mechanical means, such as the sutures and/or staples disclosed hereinabove.

An adhesive means can also be used to releasably attach the heart manipulation system element to the heart. As shown in Figure 8, surgical adhesive 60 can be placed on the element near rim 14 to releasably attach the element to heart H. A wick 62 can be included in the element to ensure the delivery of bonding activators or de-bonding agents directly to the adhesive layer. Solvent can be applied to the adhesive via wick 62 to release the adhesive from the heart as will occur to those skilled in the art based on the teaching of the present disclosure. Any suitable surgical adhesive can be used and those skilled in the art will understand what adhesive is best based on the teaching of the present disclosure. In addition, heat or light or moisture sensitive adhesives could be used to releasably attach elements of the heart manipulation system to the heart without departing from the scope of the present disclosure. The particular adhesive forms no part of the present invention and thus will not be

discussed.

As is the case above, the adhesive can be used in conjunction with or in place of the suction and/or the mechanical means for releasably attaching the element to the heart.

5 It is understood that while certain forms of the present invention have been illustrated and described herein, it is not to be limited to the specific forms or arrangements of parts described and shown. For example, tissue-gripping needles on a pad can be used to attach the elements of the heart manipulation system to the heart, such tissue-gripping needles would be self-contained and quickly deployed. These needles would work in the manner of a skin stapler but would be more convenient since they could be deployed by a mechanism on the attachment element. Such needles can be anchored to the element being attached to the heart, and released using tools similar to those used to remove small suture needles in other applications or have integrated deployment or retraction means. The needles need not be formed with a forming device but can also be of a pre-formed configuration, such as a helix, or the like and can be self-tapped into the heart. The heart attachment system is not dependent on suction alone and, as can be understood from the foregoing teaching, can include various other means in addition to, or instead of, suction. Combinations of the various mechanical and adhesive and suction means can be used as will be understood from the teaching of this disclosure.

WE CLAIM:

1. A manipulation system for cardiac surgery comprising:
 - a gross support means for engaging a beating heart and supporting the heart when the heart is located and oriented for surgery, said gross support means being located at the base of the heart and including a head which is sized and shaped to cradle the myocardium of the left ventricle along the arterialventricular groove;
 - a suspension head for lifting the heart and which is located near the apical region of the heart and at least partially overlying the right ventricle; and
 - means for releasably attaching said suspension head to the heart.
2. In a manipulation system for cardiac surgery which includes means for engaging a selected section of the heart to immobilize that selected section as a surgery target while permitting non-engaged sections of the heart to move in a manner whereby essentially unabated cardiac output is maintained while the heart is regionally immobilized, wherein the improvement comprises:
 - a suspension head means releasably attached to the surface of the beating heart to lift the heart and which is located near the apical region of the heart, said suspension head including a head abutting the surface of the beating heart, said head having means for accommodating multiplanar surface movement of the beating heart while remaining attached to the surface of the beating heart, said suspension head further including means for

accommodating multiplanar movement of the beating heart.

3. The improvement defined in Claim 1 wherein said gross support means is located adjacent to the left atrium.

4. A heart manipulation system for use in cardiac surgery comprising:

a frame that is located inside a patient during beating heart surgery and which includes means for engaging the pericardial cavity of the patient for mounting said frame on the patient to move with the patient if the patient is moved or re-oriented during surgery;

a suspension head movably mounted on said frame for lifting the heart and which is located near the apical region of the right ventricle to prevent collapse of the right ventricle during manipulation of the heart and at least partially overlying the right ventricle and which includes a flexible means for permitting multiplanar relative movement between the beating heart and means mounting the suspension head on said frame means, said suspension head including a flexible rim engaging the myocardium of the heart and being flexible in a plurality of planes so multiplanar movement of the myocardium during operation of the heart will be accommodated by said flexible rim;

means for releasably attaching said suspension head to the heart;

a means for locally engaging a selected section of the heart and locally immobilizing the heart adjacent to a surgery target

so the heart is supported and free to operate during surgery while it is also locally immobilized at the surgery target with non-engaged sections of the heart free to move in a manner whereby essentially unabated cardiac output is maintained while the heart is locally immobilized, and further including a flexible rim engaging the myocardium of the heart and being flexible in a plurality of planes so multiplanar movement of the myocardium during operation of the heart will be accommodated by the flexible rim of said means for locally engaging a selected section of the heart;

a gross support means movably mounted on said frame for engaging the heart to support the heart when the heart is oriented for surgery and which is located at the base of the heart and which cradles the myocardium of the left ventricle along the arterialventricular groove and which includes means for movably connecting said gross support means to said frame, the gross support means supporting the mitral valve annulus to maintain competent mitral valve function and is placed beneath an infolded section of myocardium, said gross support means including a handle which extends outside of the patient during surgery for adjusting the location of said gross support means, and further including a head having a malleable rod means for connecting said head to said means for mounting said gross support means on said frame, said head including a plurality of sections which are movable relative to each other and means for maintaining said sections in a selected relative orientation; and

means for releasably attaching said gross support means to the heart.

5. A heart manipulation system for use in cardiac surgery comprising:

a frame which is located inside a patient during beating heart surgery and which is mounted on the patient to move with the patient;

a suspension head mounted on said frame for lifting the beating heart and which includes a flexible head, said flexible head including a flexible rim, said flexible rim being flexible in a plurality of planes to accommodate multiplanar movement of the surface of the beating heart, and means for accommodating multiplanar movement of the beating heart during beating heart surgery;

means for releasably attaching said suspension head to the heart; and

means for engaging a selected section of the heart to immobilize that selected section as a surgery target while permitting non-engaged sections of the heart to move in a manner whereby essentially unabated cardiac output is maintained while the heart is locally immobilized.

6. The improvement defined in Claim 1 wherein the improvement further includes means for engaging a selected section of the heart to immobilize that selected section as a surgery target while permitting non-engaged sections of the heart to move in a manner whereby essentially unabated cardiac output is maintained

while the heart is regionally immobilized.

7. A manipulation system for use in cardiac surgery comprising:
a gross support means for engaging and supporting a beating heart when the heart is located and oriented for surgery and which is located at the base of the heart and engages the beating heart at a location that supports the mitral valve annulus and which includes a flexible head which is sized and shaped to extend along the arterialventricular groove of the heart;
means for immobilizing the heart adjacent to a surgery target so the heart is supported and free to operate during surgery while it is also locally immobilized at the surgery target;
means for releasably attaching said gross support means to the heart; and

a suspension head for lifting the heart and which is located near the apex of the heart and which includes a flexible head.

8. The manipulation system defined in Claim 1 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes sutures.

9. The manipulation system defined in Claim 1 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes adhesive.

10. The manipulation system defined in Claim 1 wherein said means

for releasably attaching at least one of the suspension head or the gross support means to the heart includes staples.

11. The heart manipulation system defined in Claim 4 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes sutures.

12. The heart manipulation system defined in Claim 4 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes adhesive.

13. The heart manipulation system defined in Claim 4 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes staples.

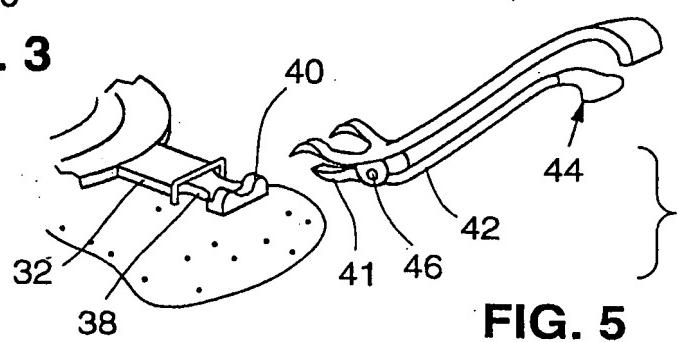
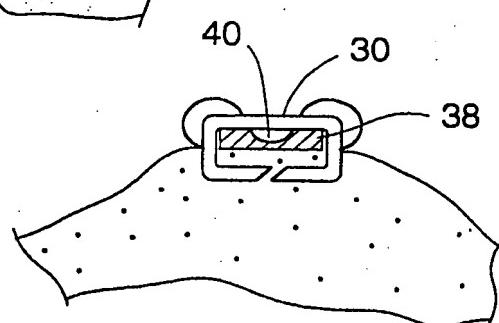
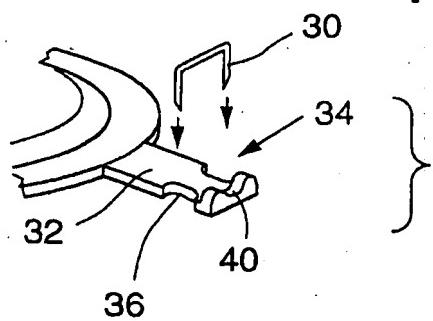
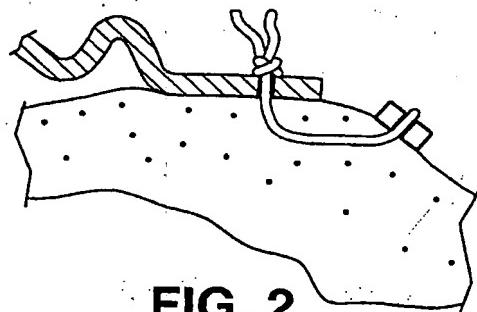
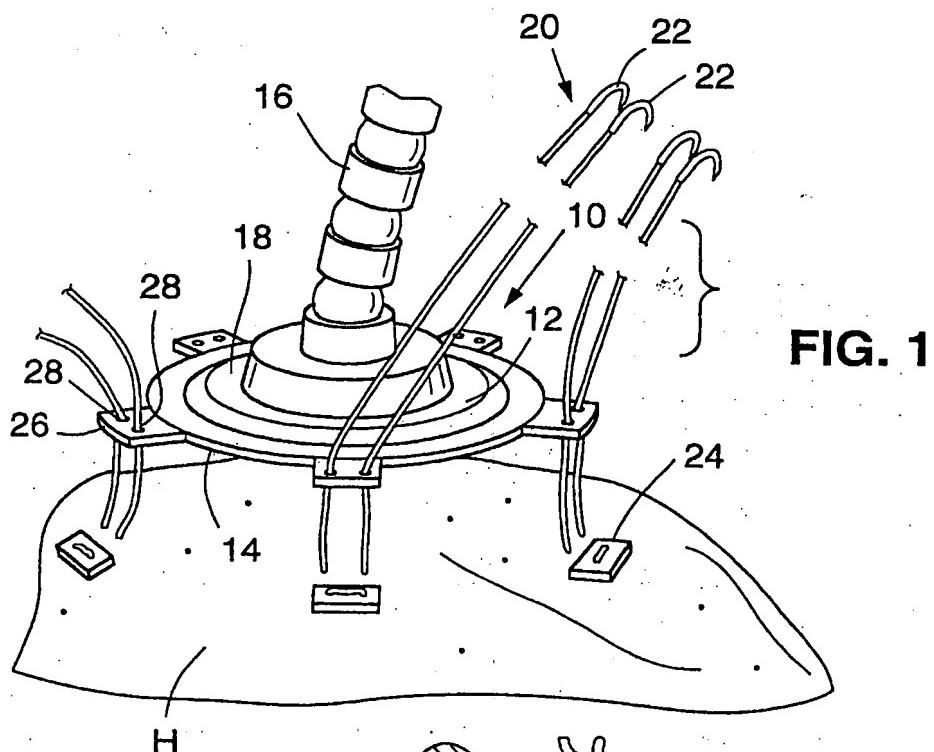
14. The heart manipulation system defined in Claim 11 further including an extension on a rim of the suspension head to which said sutures are attached.

15. The manipulation system defined in Claim 1 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes suture needles.

16. The heart manipulation system defined in Claim 4 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes suture needles.

17. The manipulation system defined in Claim 1 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes mechanical elements.
18. The heart manipulation system defined in Claim 4 wherein said means for releasably attaching at least one of the suspension head or the gross support means to the heart includes mechanical elements.
19. The manipulation system defined in Claim 1 further including a flexible means for permitting said suspension head to move in a plurality of planes to accommodate movement of the heart during beating of the heart to maintain cardiac output.

1/2



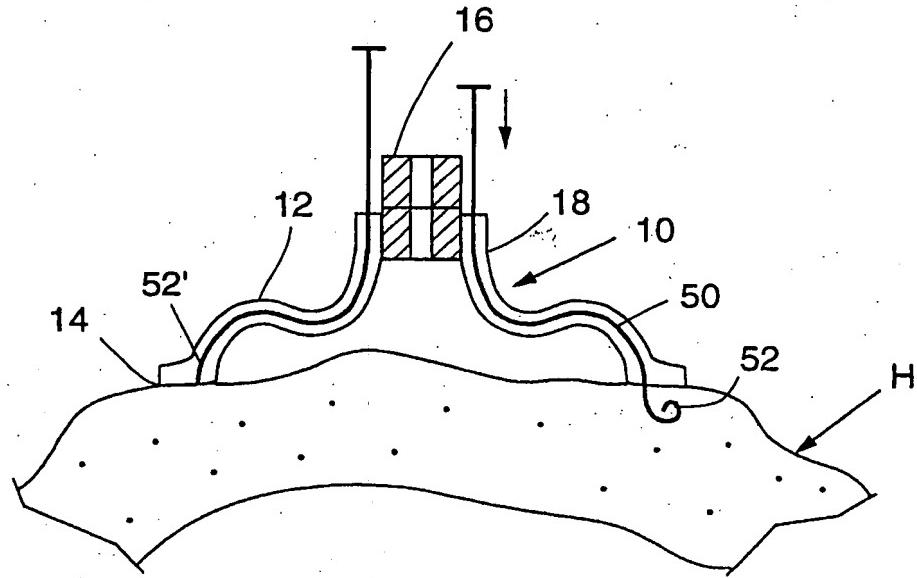


FIG. 6

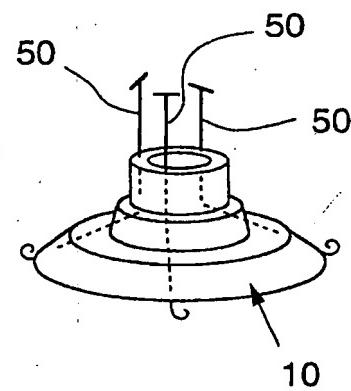


FIG. 7

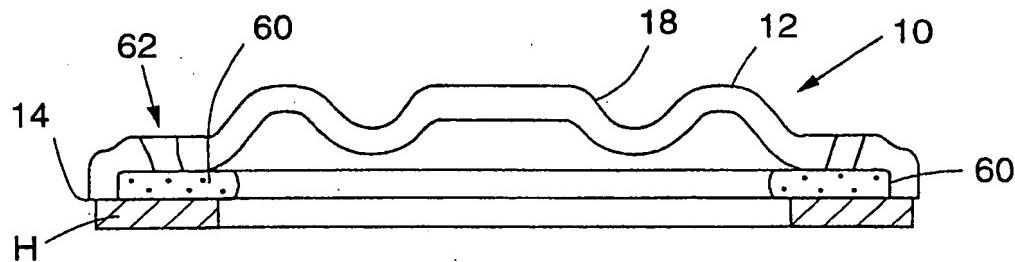


FIG. 8